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| 09/995,599      | 11/29/2001  | Masayasu Ogushi      | 216644US0           | 2699             |

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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1772

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding. -

**Office Action Summary**

Application No.

09/995,599

Applicant(s)

OGUSHI ET AL.

Examiner

Walter B. Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,8,10,11,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,10,11 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Acknowledgement of Applicant's Amendments***

1. The amendments made in claims 1 and 16 in the Amendment filed May 2, 2005 (Amdt. C) have been received and considered by Examiner.

### ***WITHDRAWN REJECTIONS***

2. The 35 U.S.C. 102(e) rejection of claims 1, 8 and 15 that was repeated in paragraph 6 of the previous Office Action mailed December 14, 2004 has been withdrawn due to Applicant's amendments in claim 1 in Amdt. C.
3. The 35 U.S.C. 103(a) rejection of claims 2, 10 and 11 that was repeated in paragraph 7 of the previous Office Action mailed December 14, 2004 has been withdrawn due to Applicant's amendments in claim 1 in Amdt. C.

### ***NEW OBJECTIONS***

#### ***Specification***

4. The amendment filed May 2, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the recitation of claim 1 that the "resin composition consist[s] essentially of" the hydrogenated styrene-isoprene-styrene block copolymer and the polypropylene. Note that the recitation that the "polypropylene consist[s] essentially of propylene monomer" is supported on page 4, lines 11-19 of the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

***NEW REJECTIONS***

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of claim 1 that the “resin composition consist[s] essentially of” the hydrogenated styrene-isoprene-styrene block copolymer and the polypropylene constitutes new matter. Note that the recitation that the “polypropylene consist[s] essentially of propylene monomer” is supported on page 4, lines 11-19 of the specification.

***Claim Rejections - 35 USC § 103***

7. Claims 1, 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Jaeger et al.

In regard to claim 1, Ahmed et al. teach medical devices (col. 1, lines 40-48) and more specifically medical tubing (col. 16, lines 15-19) (and therefore a medical tube) obtained by subjecting a resin composition consisting essentially of a hydrogenated styrene-isoprene-styrene block copolymer (col. 13, lines 57-64, col. 14, lines 23-26, 43-45 and 54-64 and col. 16, lines 64-66) and polypropylene consisting essentially of propylene monomer (col. 15, lines 25-30 and col. 16, lines 31-39) to extrusion molding (col. 15, lines 58-62 and col. 16, lines 2-13). Ahmed et al.

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teach that the tube has a storage modulus of less than  $3 \times 10^9$  dynes/cm<sup>2</sup> at 24°C (col. 15, lines 37-41), a range that encompasses the claimed storage modulus range of  $5.0 \times 10^7$  dynes/cm<sup>2</sup> to  $8.0 \times 10^8$  dynes/cm<sup>2</sup> at 25°C. Ahmed et al. teach that styrene block copolymers are strong, flexible materials that exhibit excellent elasticity over a wide range of temperatures (col. 1, lines 40-44) and that a goal of Ahmed et al. is to provide blend components that can extend available quantities of styrene block copolymers without substantially altering the key elastic properties of the styrene block copolymers (col. 2, lines 8-12).

Ahmed et al. fail to teach that the weight ratio of the polypropylene to the hydrogenated styrene-isoprene-styrene block copolymer is 20/80 to 40/60.

Jaeger et al., however, disclose an elastic film comprising a styrene-isoprene-styrene block copolymer and polypropylene where the polypropylene is present in the film in an amount ranging from 20 to 60% (col. 17, lines 3-7). Jaeger et al. disclose that improvements in tear resistance appeared at amounts of polypropylene of 35% and greater (col. 17, lines 28-31) and that addition of the polypropylene in the disclosed amounts generally did not negatively affect the tear resistance of the film (col. 17, lines 39-41). Therefore, one of ordinary skill in the art would have recognized to have blended an amount of polypropylene with the block copolymer of Ahmed et al. that results in a weight ratio of the polypropylene to the hydrogenated styrene-isoprene-styrene block copolymer is from 20/80 to 60/40 since weight ratios within this range result in a blend in which the elastic properties of the blend are not negatively affected by the polypropylene, and the tear resistance of the film is improved when the amount of polypropylene is 35% and greater, as taught by Jaeger et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended an amount of polypropylene with the block copolymer of Ahmed et al. that results in a weight ratio of the polypropylene to the hydrogenated styrene-isoprene-styrene block copolymer is from 20/80 to 60/40 since weight ratios within this range result in a blend in which the elastic properties of the blend are not negatively affected by the polypropylene, and the tear resistance of the film is improved when the amount of polypropylene is 35% and greater, as taught by Jaeger et al.

Since Ahmed et al. and Jaeger et al. teach all of the structural and compositional limitations claimed in claim 1, the tube necessarily has a ratio of the storage modulus in the extrusion direction to a storage modulus in the circumferential direction of not more than 1.3 at 25°C. The term “endotracheal” in the phrase “endotracheal tube” is an intended use recitation that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). Note that no structure is claimed which limits the claimed tube to solely an endotracheal tube. The recitations “obtained by subjecting” and “to extrusion-molding” are method limitations that have been given little patentable weight since the method of forming the tube is not germane to the issue of patentability of the tube itself. Note that the recitations “as a styrenic elastomer” and “as a polyolefin” do not further limit the composition recited by the phrase “a hydrogenated styrene-isoprene-styrene block copolymer” or the composition recited by the term “polypropylene”.

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In regard to claim 8, Ahmed et al. teach that the hydrogenated styrene-isoprene-styrene block copolymer comprises a styrenic polymer block and that the content of the styrenic polymer block is 30% by weight (col. 16, lines 64-66), a value that falls within the claimed range of 10 to 40% by weight.

In regard to claim 15, Ahmed et al. teach that the hydrogenated styrene-isoprene-styrene block copolymer comprises a hydrogenated polyisoprene block made of polyisoprene (col. 14, lines 43-44 and col. 16, lines 64-66) and that the polyisoprene block is hydrogenated such that at least 80% of the carbon-carbon double bonds of the polyisoprene are hydrogenated (col. 14, lines 54-64), a range that overlaps with the claimed range of “not less than 70%”.

8. Claims 2, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Jaeger et al. and in further view of Sterling.

Ahmed et al. and Jaeger et al. teach the tube as discussed above. Ahmed et al. teach that blow molding is a suitable method of forming the composition into an article (col. 15, line 64-col. 16, line 10).

In regard to claim 2, Ahmed et al. and Jaeger et al. fail to teach that the tube is provided with a cuff formed from the resin composition comprising a styrenic elastomer and a polyolefin on the outer peripheral surface of the tube, that the cuff has a storage modulus of not more than  $5.0 \times 10^8$  dynes/cm<sup>2</sup> at 25°C and that the resin composition of the cuff has a melt tension of not less than 1g at 230°C. Sterling, however, discloses an endotracheal tube (item 33) having a shaft (item 34) and a cuff (item 41) that is formed on the outer peripheral surface of the tube that are both formed from a blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene (col. 7, lines 1-4 and 27-31, col. 15, lines 17-36 and 52-60 and Fig. 6 and 15).

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Sterling discloses that the blend comprising styrene-ethylene-butylene-styrene block copolymer and polyolefin can undergo conventional blow molding techniques (col.14, line 58-col. 15, line 7). Therefore, one of ordinary skill in the art would have recognized to have blow molded the resin composition comprising a styrenic elastomer and polypropylene taught by Ahmed et al. and Jaeger et al. which has a storage modulus of not more than  $5.0 \times 10^8$  dynes/cm<sup>2</sup> at 24°C into a cuff in order to form the medical tube of Ahmed et al. into an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that is on the outer peripheral surface of the endotracheal tube that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blow molded the resin composition comprising a styrenic elastomer and polypropylene taught by Ahmed et al. and Jaeger et al. which has a storage modulus of not more than  $5.0 \times 10^8$  dynes/cm<sup>2</sup> at 24°C into a cuff in order to form the medical tube of Ahmed et al. into an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that is on the outer peripheral surface of the endotracheal tube that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

The recitations “obtained by subjecting” and “to blow-molding” are method limitations that have been given little patentable weight since the method of forming the cuff is not germane to the issue of patentability of the cuff itself.

In regard to the claimed melt tension of the resin composition of the cuff of not less than 1g at 230°C, the selection of polymeric compositions having suitable melt tension for the particular desired end use would have been obvious to one of ordinary skill in the art at the time



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the invention was made, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regard to claims 10 and 11, Ahmed et al. teach that additives such as fillers can be included in the resin composition (col. 15, lines 50-58). Ahmed et al. and Jaeger et al. fail to teach that the filler is present in an amount of 5 to 20% by weight (as claimed in claim 10) and that the filler is one of the chemical species claimed in claim 11. Sterling, however, discloses that the block copolymer/polypropylene blend contains up to 25% polystyrene as an additive (col. 4, lines 54-55) that improves the rheological properties of the blend (col. 11, lines 5-6). Sterling discloses that the polymeric components (i.e. the elastomeric block copolymer, the polypropylene and the polystyrene additive) are introduced as a mixture in pellet form (col. 11, lines 26-32), which Examiner interprets to be structurally equivalent to beads as claimed. Therefore, one of ordinary skill in the art would have recognized to have added crosslinked polystyrene beads in an amount of 5 to 20% by weight to the composition taught by Ahmed et al. and Jaeger et al. in order to improve the rheological properties of the blend as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added crosslinked polystyrene beads in an amount of 5 to 20% by weight to the composition taught by Ahmed et al. and Jaeger et al. in order to improve the rheological properties of the blend as taught by Sterling.

***Response to Arguments***

9. Applicant's arguments regarding the 35 U.S.C. 102(e) rejection of claims 1, 8 and 15 presented on pages 5-8 of Amdt. C are moot due to the withdrawal of the rejection in this Office Action.

10. Applicant's arguments regarding the Sterling reference with regard to the rejection of claim 1 presented on page 8 of Amdt. C are irrelevant because Sterling is not relied upon in a rejection of claim 1.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-

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1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh  
08/05/05

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